



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA-HQ-OPPT-2020-0302; FRL-10022-76]

RIN 2070-AB27

Modification of Significant New Uses of Certain Chemical Substances (20-2.M)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is amending significant new use rules (SNURs) issued under the Toxic Substances Control Act (TSCA) for certain chemical substances identified herein, which were the subject of premanufacture notices (PMNs) and significant new use notices (SNUNs). This action would amend the SNURs to allow certain new uses reported in the SNUNs without additional notification requirements and modify the significant new use notification requirements based on the actions and determinations for the SNUN submissions. EPA is issuing these amendments based on review of new and existing data for the chemical substances.

DATES: This rule is effective on [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. For purposes of judicial review, this rule shall be promulgated at 1 p.m. (e.s.t.) on [INSERT DATE 14 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* William Wysong, New Chemicals Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-4163; email address: wysong.william@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture, process, or use the chemical substances contained in this rule. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Manufacturers or processors of one or more subject chemical substances (NAICS codes 325 and 324110), *e.g.*, chemical manufacturing and petroleum refineries.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA, which would include the SNUR requirements. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import provisions. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, pursuant to 40 CFR 721.20, any persons who export or intend to export a chemical substance that is the subject of this rule are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

B. How can I access the docket?

The docket includes information considered by the Agency in developing the proposed and final rules. The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2020-0302, is available at <https://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is

(202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket available at <https://www.epa.gov/dockets>.

Due to the public health emergency, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

II. Background

A. What action is the Agency taking?

EPA is issuing amendments to the SNURs for certain chemical substances in 40 CFR part 721 subpart E.

Previously, in the *Federal Register* of November 18, 2020 (85 FR 73439) (FRL-10013-54), EPA proposed amendments to the SNURs for these chemical substances and established the record for these SNUR amendments in the docket under docket ID number EPA-HQ-OPPT-2020-0302. That docket includes information considered by the Agency in developing the proposed and final rules, including public comments.

B. What is the Agency's authority for taking this action?

TSCA section 5(a)(2) (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a “significant new use.” EPA must make this determination by rule (*i.e.*, a SNUR) after considering all relevant factors, including those listed in TSCA section 5(a)(2). EPA may also amend a SNUR promulgated under TSCA section 5(a)(2). Procedures and criteria for modifying or revoking SNUR requirements appear at 40 CFR 721.185. Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a SNUN to EPA at least 90 days before they manufacture, import, or process the chemical substance for that use. Persons who must report are described in 40 CFR 721.5.

C. Do the SNUR general provisions apply?

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the final rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the final rule. Provisions relating to user fees appear at 40 CFR part 700. According to 40 CFR 721.1(c), persons subject to these SNURs must comply with the same notice requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA sections 5(b) and 5(d)(1), the exemptions authorized by TSCA sections 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA must either determine that the significant new use is not likely to present an unreasonable risk of injury or take such regulatory action as is associated with an alternative determination before the manufacture or processing for the significant new use can commence. If EPA determines that the significant new use is not likely to present an unreasonable risk, EPA is required under TSCA section 5(g) to make public, and submit for publication in the *Federal Register*, a statement of EPA's findings.

III. Significant New Use Determination

A. Determination Factors

TSCA section 5(a)(2) states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In determining whether and how to modify the significant new uses for the chemical substances that are the subject of these SNURs, EPA considered relevant information about the toxicity of the chemical substance, likely human exposures and environmental releases associated with possible uses, and the four TSCA section 5(a)(2) factors listed in this unit.

B. Procedures for Significant New Uses claimed as Confidential Business Information (CBI)

By this rule, EPA is establishing certain significant new uses which have been claimed as CBI subject to Agency confidentiality regulations at 40 CFR part 2 and 40 CFR part 720, subpart E. Absent a final determination or other disposition of the confidentiality claim under 40 CFR part 2 procedures, EPA is required to keep this information confidential. EPA promulgated a procedure to deal with the situation where a specific significant new use is CBI, at 40 CFR 721.1725(b)(1) and has referenced it to apply to other SNURs.

Under these procedures a manufacturer or processor may request EPA to determine whether a proposed use would be a significant new use under the rule. The manufacturer or processor must show that it has a *bona fide* intent to manufacture or process the chemical substance and must identify the specific use for which it intends to manufacture or process the chemical substance. If EPA concludes that the person has shown a *bona fide* intent to manufacture or process the chemical substance, EPA will tell the person whether the use identified in the *bona fide* submission would be a significant new use under the rule. Since most of the chemical identities of the chemical substances subject to these SNURs are also CBI, manufacturers and processors can combine the *bona fide* submission under the procedure in 40 CFR 721.1725(b)(1) with that under 40 CFR 721.11 into a single step.

If EPA determines that the use identified in the *bona fide* submission would not be a significant new use, *i.e.*, the use does not meet the criteria specified in the rule for a significant new use, that person can manufacture or process the chemical substance so long as the significant new use trigger is not met. In the case of a production volume trigger, this means that the production volume limit is not exceeded by the amount identified in the *bona fide* submission

to EPA. Because of confidentiality concerns, EPA does not typically disclose the actual production volume that constitutes the use trigger. Thus, if the person later intends to exceed that volume, a new *bona fide* submission would be necessary to determine whether that higher volume would be a significant new use.

IV. Public Comments

EPA received three public comments in response to the proposed SNURs. None of the comments pertained to the proposed SNURs or the basis for these SNURs. As a result, EPA is finalizing the rules as proposed and is not responding to the comments.

V. Rationale of the Final Rule

These amendments are based on EPA's determination under 40 CFR 721.85(a)(3) that significant new use notices for some of the activities designated as significant new uses of the relevant chemical substances were submitted to EPA and after reviewing the notices, EPA concluded that there is no need to require additional notice from persons who propose to engage in identical or similar activities. In those instances where EPA expanded the scope of the significant new use, the Agency identified concerns, as discussed in Unit IV. of the proposed rule, associated with certain potential new uses. In addition to considering the factors discussed in Unit IV. of the proposed rule, EPA determined that those uses could result in changes in the type or form of exposure to the chemical substance, increased exposures to the chemical substance, and/or changes in the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of the chemical substance.

VI. Applicability of Rules to Uses Occurring Before Effective Date of the Final Rule

To establish a significant new use, EPA must determine that the use is not ongoing. EPA solicited comments on the proposed rule, providing an opportunity for members of the public to indicate whether any of the uses which are not significant new uses under the current rules, but which would be regulated as "significant new uses" if the proposed rule is finalized, are ongoing. EPA received no comments that these uses were ongoing. Therefore, EPA concludes that the

uses are not ongoing.

EPA designated November 18, 2020 (the date of publication of the proposed rule) as the cutoff date for determining whether the new use is ongoing. The objective of EPA's approach has been to ensure that a person could not defeat a SNUR by initiating a significant new use before the effective date of the final rule.

In the unlikely event that a person began commercial manufacture or processing of the chemical substances for a significant new use identified as of the cutoff date, that person will have to cease any such activity upon the effective date of the final rule. To resume their activities, that person would have to first comply with all applicable SNUR notification requirements and wait until EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken such actions as are required with that determination.

VII. Development and Submission of Information

EPA recognizes that TSCA section 5 generally does not require development of any particular new information (*e.g.*, generating test data) before submission of a SNUN. There is an exception: If a person is required to submit information for a chemical substance pursuant to a rule, order or consent agreement under TSCA section 4, then TSCA section 5(b)(1)(A) requires such information to be submitted to EPA at the time of submission of the SNUN.

In the absence of a rule, order, or consent agreement under TSCA section 4 covering the chemical substance, persons are required only to submit information in their possession or control and to describe any other information known to or reasonably ascertainable by them (see 40 CFR 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. Unit IV. of the proposed rule lists potentially useful information for all SNURs addressed in this final rule. Descriptions are provided for informational purposes. The information identified in Unit IV. of the proposed rule will be potentially useful to EPA's evaluation of a chemical substance in the event that someone submits a SNUN for a significant new use pursuant to the SNURs addressed in this final rule. Companies who are considering

submitting a SNUN are encouraged, but are not required, to develop the potentially useful information on the substance.

EPA strongly encourages persons, before performing any testing, to consult with the Agency. Furthermore, pursuant to TSCA section 4(h), which pertains to reduction of testing on vertebrate animals, EPA encourages consultation with the Agency on the use of alternative test methods and strategies (also called New Approach Methodologies, or NAMs), if available, to generate the recommended test data. EPA encourages dialogue with Agency representatives to help determine how best the submitter can meet both the data needs and the objective of TSCA section 4(h). For more information on alternative test methods and strategies to reduce vertebrate animal testing, visit <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/alternative-test-methods-and-strategies-reduce>.

The potentially useful information identified in Unit IV. of the proposed rule may not be the only means of addressing the potential risks of the chemical substance. However, submitting a SNUN without any test data or other information may increase the likelihood that EPA will take action under TSCA sections 5(e) or 5(f). EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs that provide detailed information on the following:

- Human exposure and environmental release that may result from the significant new use of the chemical substances; and

VIII. SNUN Submissions

According to 40 CFR 721.1(c), persons submitting a SNUN must comply with the same notification requirements and EPA regulatory procedures as persons submitting a PMN under 40 CFR part 720, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted on EPA Form No. 7710-25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40

CFR 721.25 and 720.40. E-PMN software is available electronically at

<https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca>.

IX. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers and processors of the chemical substances subject to this rule. EPA's complete economic analysis is available in the docket for this rulemaking.

X. Statutory and Executive Order Reviews

Additional information about these statutes and Executive orders can be found at <https://www.epa.gov/laws-regulations-and-executive-orders>.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulations and Regulatory Review

This action modifies SNURs for several new chemical substances that were the subject of PMNs and SNUNs. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act (PRA)

According to the PRA, (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the *Federal Register*, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable.

The information collection activities associated with these SNURs have already been approved by OMB pursuant to the PRA under OMB control number 2070-0012 (EPA ICR No. 574). This action does not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30

and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

The listing of the OMB control numbers of the collection instruments and their subsequent codification in the table in 40 CFR 9.1 satisfies the display requirements of the PRA and OMB's implementing regulations at 5 CFR part 1320. Since this ICR was previously subject to public notice and comment prior to OMB approval, and given the technical nature of the table in 40 CFR part 9, EPA finds that further notice and comment to amend it is unnecessary. As a result, EPA finds that there is “good cause” under section 553(b)(3)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)) to amend this table in 40 CFR 9.1 without further notice and comment.

C. Regulatory Flexibility Act (RFA)

Pursuant to the RFA section 605(b), 5 U.S.C. 601 *et seq.*, I hereby certify that promulgation of this SNUR would not have a significant adverse economic impact on a substantial number of small entities. The requirement to submit a SNUN applies to any person (including small or large entities) who intends to engage in any activity described in the final rule as a “significant new use”. Because these uses are “new,” based on all information currently available to EPA, it appears that no small or large entities presently engage in such activities. A SNUR requires that any person who intends to engage in such activity in the future must first notify EPA by submitting a SNUN. Although some small entities may decide to pursue a significant new use in the future, EPA cannot presently determine how many, if any, there may be. However, EPA’s experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemicals, the Agency receives only a small number of notices per year. For example, the number of SNUNs received was seven in Federal fiscal year (FY) 2013, 13 in FY2014, six in FY2015, 12 in FY2016, 13 in FY2017, and 11 in FY2018. Only a fraction of these were from small businesses. In addition, the Agency currently offers relief to qualifying

small businesses by reducing the SNUN submission fee from \$16,000 to \$2,800. This lower fee reduces the total reporting and recordkeeping of cost of submitting a SNUN to about \$10,116 for qualifying small firms. Therefore, the potential economic impacts of complying with this SNUR are not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published in the *Federal Register* of June 2, 1997 (62 FR 29684) (FRL-5597-1), the Agency presented its general determination that final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

D. Unfunded Mandates Reform Act (UMRA)

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by this action. As such, EPA has determined that this action does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq.*).

E. Executive Order 13132: Federalism

This action will not have federalism implications because it is not expected to have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999).

F. Executive Order 13175: Consultation and Coordination with Indian Tribe Governments

This action will not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes, significantly or uniquely affect the communities of Indian Tribal governments, and does not involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175 (65 FR 67249, November 9, 2000), do not apply to this action.

G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use and because this action is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

Since this action does not involve any technical standards, NTTAA section 12(d) (15 U.S.C. 272 note), does not apply to this action.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994).

K. Congressional Review Act (CRA)

This action is subject to the CRA (5 U.S.C. 801 *et seq.*), and EPA will submit a rule report containing this rule and other required information to each House of the Congress and to the Comptroller General of the United States. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and

recordkeeping requirements.

Dated: May 25, 2021.

Tala Henry,

Deputy Director, Office of Pollution Prevention and Toxics.

Therefore, for the reasons stated in the preamble, 40 CFR chapter I is amended as follows:

PART 721--SIGNIFICANT NEW USES OF CHEMICAL SUBSTANCES

1. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

2. Amend § 721.983 by revising paragraphs (a)(1) and (a)(2)(ii) to read as follows:

§ 721.983 Sulfonyl azide intermediate (generic).

(a) *** (1) The chemical substance identified generically as sulfonyl azide intermediate (PMN P-99-1202 and SNUN S-15-6) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) * * *

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f). It is a significant new use to import, process, or use this chemical substance as a powder unless less than 1% of particles by weight are less than 200 microns.

* * * * *

3. Amend § 721.9675 by revising paragraphs (a)(1), (a)(2)(i), (a)(2)(ii) and (b)(1) to read as follows:

§ 721.9675 Titanate [TiO₂ (2-)], dipotassium.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as titanate [TiO₂ (2-)], dipotassium (PMN P-90-226; SNUNs P-96-1408, S-08-6, S-09-4, S-13-49, S-16-5, and S-17-6; CAS No. 12056-51-8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) * * *

(i) *Protection in the workplace.* For manufacturing, processing, and use of SN-17-6: Requirements as specified in § 721.63(a)(4), (5), (6), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(4), engineering control measures

(e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health assigned protection factor of at least 10. For purposes of § 721.63(a)(6), the airborne form(s) of the substance include particulate (including solid or liquid droplets).

(A) As an alternative to the respirator requirements in paragraph (a)(2)(i) of this section, a manufacturer or processor may choose to follow the new chemical exposure limit (NCEL) provision listed in the TSCA section 5(e) consent order for this substance. The NCEL is 0.8 mg/m³ as an 8-hour time weighted average. Persons who wish to pursue NCELs as an alternative to § 721.63 respirator requirements may request to do so under § 721.30. Persons whose § 721.30 requests to use the NCELs approach are approved by EPA will be required to follow NCELs provisions comparable to those contained in the corresponding TSCA section 5(e) consent order.

(B) [Reserved]

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f) and (l). In addition, a significant new use of the substance is importation of the chemical substance if:

(A) Manufactured by other than the method described in premanufacture notice P-90-226 and significant new use notices P-96-1408, S-08-6, S-09-4, S-13-49, S-16-5, and S-17-6.

(B) Manufactured producing respirable, acicular fibers with an average aspect ratio of greater than 5. The average aspect ratio is defined as the ratio of average length to average diameter. For manufacture of S-17-6: Manufacture with a particle size distribution containing greater than 30% of particles less than 10 microns.

(b) * * *

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (d)

and (i) are applicable to manufacturers and processors of this substance.

* * * * *

4. Amend § 721.10288 by revising paragraphs (a)(1) and (a)(2)(i) to read as follows:

§ 721.10288 Cyclohexane, oxidized, by-products from, distn. residues.

(a) *** (1) The chemical substance identified as cyclohexane, oxidized, by-products from, distn. residues (PMN P-11-316; CAS No. 1014979-92-0) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) * * *

(i) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N = 470.

* * * * *

5. Amend §721.10432 by:

- a. Revising paragraphs (a)(1), (a)(2)(i) and (a)(2)(ii);
- b. Adding paragraphs (a)(2)(iii) and (iv); and
- c. Revising paragraph (b)(1).

The revisions and additions read as follows:

§ 721.10432 1,2,4,5,7,8-Hexoxonane, 3,6,9-triethyl-3,6,9-trimethyl-

(a) *** (1) The chemical substance identified as 1,2,4,5,7,8-hexoxonane, 3,6,9-triethyl-3,6,9-trimethyl- (PMN P-98-1028 and SNUNs S-14-9, S-17-12, and S-17-15; CAS No. 24748-23-0) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) * * *

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(3) through (5), (a)(6)(v), (b), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (4), engineering control measures (*e.g.*, enclosure or confinement of the operation, general and local ventilation) or administrative control measures

(e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health assigned protection factor of at least 50. For purposes of § 721.63(b), the concentration is set at 1.0%.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1) through (3), (g)(4)(i), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), the required human health hazard statements include: internal organ effects; reproductive effects; allergic skin reaction. For purposes of § 721.72(g)(2), the required human health precautionary statements include: use skin protection; where engineering controls are not determined to be adequate, use respiratory protection. For purposes of § 721.72(g)(3), the required environmental hazard statements include: this substance may cause long lasting harmful effects to aquatic life. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial commercial, and consumer activities.* It is a significant new use to process or use the substance with an application method that generates a mist, vapor, or aerosol.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N=56.

(b) * * *

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers and processors of this substance.

* * * * *

6. Amend § 721.10907 by revising paragraphs (a)(1) and (a)(2)(i) to read as follows:

§ 721.10907 Polyfluorohydrocarbon (generic).

(a) *** (1) The chemical substance identified generically as polyfluorohydrocarbon (PMN P-15-326 and SNUN S-17-11) is subject to reporting under this section for the significant

new uses described in paragraph (a)(2) of this section.

(2) * * *

(i) *Industrial commercial, and consumer activities.* Requirements as specified in § 721.80(o). It is a significant new use to use the substance other than for the confidential uses described in PMN P-15-326 and SNUN S-17-11.

* * * * *

7. Amend § 721.10922 by:

- a. Revising paragraphs (a)(1), (a)(2)(i) and (a)(2)(ii);
- b. Adding paragraphs (a)(2)(iii) and (iv);
- c. Revising paragraph (b)(1); and
- d. Removing paragraph (b)(3).

The revisions and additions read as follows:

§ 721.10922 1,2,4,5,7,8-Hexoxonane, 3,6,9-trimethyl-, 3,6,9-tris(alkyl) derivs. (generic).

(a) *** (1) The chemical substance identified generically as 1,2,4,5,7,8-hexoxonane, 3,6,9-trimethyl-, 3,6,9-tris(alkyl) derivs. (PMN P-15-607 and SNUN S-17-13) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) * * *

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(3) through (5), (a)(6)(v), (b), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (4), engineering control measures (*e.g.*, enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.*, workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health assigned protection factor of at least 50. For purposes of § 721.63(b), the concentration is set at 1.0%.

(ii) *Hazard communication*. Requirements as specified in § 721.72(a) through (f), (g)(1) through (3), (g)(4)(i), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), the required human health hazard statements include: internal organ effects; reproductive effects; allergic skin reaction. For purposes of § 721.72(g)(2), the required human health precautionary statements include: use skin protection; where engineering controls are not determined to be adequate, use respiratory protection. For purposes of § 721.72(g)(3), the required environmental hazard statements include: this substance may cause long lasting harmful effects to aquatic life. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial commercial, and consumer activities*. It is a significant new use to process or use the substance with an application method that generates a mist, vapor, or aerosol.

(iv) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N=56.

(b) * * *

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (i) and (k) are applicable to manufacturers and processors of this substance.

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